

CLAIMS

1. A process for producing a fine dispersion of a poorly soluble drug, characterized by comprising the steps of: suspending a poorly soluble drug in a liquid containing no deflocculant to obtain a suspension; introducing the suspension into a high-pressure homogenizer to subject the same to high-pressure treatment to obtain a dispersion; and adding a deflocculant to the dispersion to deagglomerate aggregated particles contained therein.
2. The process according to Claim 1, wherein the deflocculant is a synthetic polymer or a natural polysaccharide.
3. The process according to Claim 2, wherein the synthetic polymer is a natural polysaccharide derivative, a vinyl polymer derivative or a copolymer of polyalkylene glycol.
4. The process according to any one of Claims 1 to 3, wherein the poorly soluble drug is a synthetic antibacterial agent, antifungal agent, antirheumatic agent, anti-inflammatory agent or gastrointestinal agent.
5. The process according to any one of Claims 1 to 3, wherein the poorly soluble drug is a synthetic antibacterial agent, antirheumatic agent or antifungal agent.
6. The process according to any one of Claims 4 to 5, wherein the antifungal agent is a triazole

antifungal agent or polyene antifungal agent.

7. The process according to any one of Claims 1 to 3, wherein the poorly soluble drug is a synthetic antibacterial agent.

8. The process according to any one of Claims 1 to 3, wherein the poorly soluble drug is 1-cyclopropyl-8-methyl-7-[5-methyl-6-(methylamino)-3-pyridinyl]-4-oxo-1,4-dihydro-3-quinolinecarboxylic acid, itraconazole, amphotericin B, griseofulvin or iguratimod.

9. The process according to any one of Claims 1 to 3, wherein the poorly soluble drug is iguratimod.

10. The process according to any one of Claims 1 to 3, wherein the poorly soluble drug is 1-cyclopropyl-8-methyl-7-[5-methyl-6-(methylamino)-3-pyridinyl]-4-oxo-1,4-dihydro-3-quinolinecarboxylic acid.

11. The process according to any one of Claims 1 to 7, wherein the poorly soluble drug is a drug having a solubility in water at 20°C of lower than 0.1 mg/mL.

12. A fine dispersion of a poorly soluble drug obtainable by the process according to any one of Claims 1 to 11.

13. The fine dispersion of a poorly soluble drug according to Claim 12, characterized in that 90% by volume or more of particles in the fine dispersion is less than 1000 nm in particle diameter.

14. The fine dispersion of a poorly soluble drug according to Claim 12, characterized in that 90% by

volume or more of particles in the fine dispersion is less than 500 nm in particle diameter.

15. A medicinal preparation comprising a poorly soluble drug in a form of fine particles, which is obtainable by the process according to any one of Claims 1 to 11.

16. A fine dispersion of iguratimod, characterized in that 90% by volume or more of particles in the fine dispersion is less than 1000 nm in particle diameter.

17. A fine dispersion of 1-cyclopropyl-8-methyl-7-[5-methyl-6-(methylamino)-3-pyridinyl]-4-oxo-1,4-dihydro-3-quinolinecarboxylic acid, characterized in that 90% by volume or more of particles in the fine dispersion is less than 1000 nm in particle diameter.